K090174

SEP 14 2009

510(k) Summary

Date: January 9th, 2009

Contact Person: David D. Dalise
President Owner
OCO Biomedical, Inc.

Trade Name: **TSI & ERI**
Common Name: Dental Implant
Classification Name: Dental Implant Endosseous, Root-Form

Substantial Equivalence to:

Immediate Stabilizing Implant (ISI)	K033392 (Cleared 12/11/03)
OCO 5.0mm Taper Implant	K023336 (Cleared 10/9/02)
MeggaGen ExFeel	K052369 (Cleared 1/10/06)

Description of Device:

The TS1 & ERI implants are self-tapping, commercially pure. CP Titanium or Titanium Alloy threaded screws. with light grit blasting or roughened surface treatment. The TSI includes a 2mm collar and is available in 3.25, 4.0. 5.0mm diameters and each are available in 8. 10. 12. 14. and 16mm len gths. The ERI includes a l mm collar and is available in 3.25. 4.0. 5.0mm diameters and each are available in 8. 10. 12. 14. and 16mm lengths.

Indications for Use:

The TSI and ERI Dental Implants are artificial root structures intended for permanent surgical implantation in the bone for the purpose of single or multiple tooth replacements (splinted or free standing), or for stabilization of a prosthetic system, such as artificial teeth in order to restore the patient's chewing function. The TSI and ERI can be placed in the anterior or posterior mandible/maxilla for immediate or delayed loading purposes.

Immediate loading is only intended when good primary stability is achieved and appropriate occlusal loading.

Substantial Equivalence:
OCO Biomedical. Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices. the TSI & ERI are substantially equivalent in indications and design principles to predicate devices previously cleared by the FDA: Immediate Stabilizing Implant (ISI) K033392 (Cleared 12/11/03), and OCO 5.0mm Taper Implant K023336 (Cleared 109/02). and MegaGen ExFeel K052369 (Cleared 1/10/06).

The TSI & ERI have the following similarities to the predicate devices:
-has the same intended use

-incorporates the same materials and design
-is packaged and sterilized using the same materials and processes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 14 2009

Mr. Jack Bloom
OCO Biomedical, Incorporated
8500 Washington Street NE, Suite A-1,
Albuquerque, New Mexico 87113

Re: K090174
Trade/Device Name: TSI & ERI
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: August 27, 2009
Received: August 31, 2009

Dear Mr. Bloom:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090174

Indications For Use

510(k) Number: K090174

Device Name: TSI & ERI

Indications for use:

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Prescription Use X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH. Office of Device Evaluation (ODE)

Susan Runner

ivision Sign-Off)
vision of Anesthesiology, General Hospital
ntection Control, Dental Devices

10(k) Number: K090174